[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT INFORMATION SHEET

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Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator [name and telephone number here]

You are being invited to take part in a research study while you are here as a patient in the intensive care unit. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and, if you wish, to discuss it with your relatives or friends. Ask us if there is anything that is unclear or if you would like more information. Thank you for reading this.

What is the purpose of the study?
Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in Intensive Care Units in the UK, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Research Ethics Committee.

Why have I been chosen?
Your doctors believe that it will take another 7 or more days before you will be able to breathe on your own without any help from a ventilator (breathing machine).

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form, a copy of the consent form will be given to you.

What will happen to me if I take part?
Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People are put into groups and then compared. The groups are selected by a computer that will decide on a chance basis (as if it were tossing a coin) whether you will receive an "early" tracheostomy (on day 1-4 of your ICU stay), or a "late" tracheostomy after you have been in the Intensive Care Unit for 10 days or more. If you are in the "late" group you may not need a tracheostomy at all. Once we know what group you are in we will treat you accordingly. All other care will continue in the usual manner. There are no extra tests involved in taking part in this research. The chances of being selected for either group are equal.

As part of the study routine information on your treatment will be collected. In addition, appropriate personal identifying details will be collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

What do I have to do?
You do not have to do anything yourself. The doctors and nurses on the Intensive Care Unit will keep you informed at all times.

What are the possible risks and benefits of taking part?
This trial is evaluating the best time to perform a tracheostomy. The risks related to the tracheostomy procedure are the same whether you take part in the study, or have a tracheostomy outside of the study. The possible risks of taking part in the study is that there is a small chance you might not have needed a tracheostomy as early as the first four days of your ICU stay. The potential benefit of taking part is that by having a tracheostomy early you may require less sedative drugs during your ICU stay.

What if something goes wrong?
This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part be kept confidential?
All information that is collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?
The study is estimated to take around three years, it started in the Autumn of 2004. It is hoped to publish the results in 2008 on the Intensive Care Society's web page (www.ics.ac.uk). If you would like a copy of the published results, please contact the Principal Local Investigator (name given above).

Who is funding the study?
The Medical Research Council and the Intensive Care Society, a UK charity, have both contributed to the funding of this study.

Contact for further information
If you would like further information, please feel free to contact [Principal Local Investigator name and telephone number], the consultant leading the study on this unit.